June 13, 2019

LeMaitre Vascular Inc.
Xiang Zhang
Vice President of Regulatory Affairs
63 Second Ave
Burlington, Massachusetts 01803

Re: K183513
Trade/Device Name: DuraSure Biologic Patch
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: May 8, 2019
Received: May 14, 2019

Dear Xiang Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew Krueger, M.S.E
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183513

Device Name
DuraSure Biologic Patch

Indications for Use *(Describe)*
The DuraSure Biologic Patch is intended for use as a surgical patch material to close dura mater during neurosurgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary K183513

Submitter's Information **Name:** **Address:** **Phone:** **Fax:**	 LeMaitre Vascular, Inc. 63 Second Avenue, Burlington, MA 01803 781-425-1706 781-425-5049
Contact Person:	Xiang (Vic) Zhang VP of Regulatory Affairs LeMaitre Vascular, Inc. Email: xzhang@lemaitre.com
Date Prepared: **Device Name:**	May 8, 2019 DuraSure Biologic Patch
Trade Name:	DuraSure Biologic Patch
Common Name:	Dura Substitute
Regulation Number: **Classification Panel:** **Class:** **Product Code:** **Establishment Registration**: **Establishment:**	21CFR §882.5910 Neurology II (2) GXQ 1220948 63 Second Avenue Burlington, MA 01803
Predicate Device:	Dura-Guard Dura Repair Patch K973706
Reference Device:	XenoSure Biologic Patch K040835

Device Description:	The DuraSure consists of one piece of bovine pericardial tissue that has been selected for minimal tissue blemishes. The tissue is treated with a glutaraldehyde process which crosslinks the collagen fibers and minimizes antigenicity. The DuraSure is liquid chemical sterilized and packaged in a plastic jar containing sterile glutaraldehyde storage solution. The DuraSure is designed to repair the body's natural organs.
Indication for Use:	The DuraSure Biologic Patch is intended for use as a surgical patch material to close dura mater during neurosurgery.
Summary of Technological Characteristics:	Comparisons of the DuraSure Biologic Patch with the predicate Dura-Guard Patch show that technological characteristics such as materials, biocompatibility, performance, and sterilization of the proposed device are substantially equivalent to the predicate device. The difference between the proposed device and the predicate device is: • The DuraSure biologic patch is stored in glutaraldehyde solution and the Dura-Guard is stored in propylene oxide solution. This difference does not raise additional risk concern because DuraSure biologic patch has satisfactory biocompatibility results and in-vivo animal study results.

	Proposed Device Product Name: **DuraSure Biologic Patch**	**Predicate Device** Product Name: **Dura-Guard Patch**	**Comparison**
Manufacturer	LeMaitre Vascular Inc.	Synovis/Baxter	
Clearance	This submission	K973706	
Indications for Use	The XenoSure Dura Biologic Patch is intended for use as a surgical patch material to close dura mater during neurosurgery.	For use as a dura substitute for the closure of dura mater during neurosurgery.	Same
Common Name	Dura Substitute	Dura Substitute	Same
Classification	II (2)	II (2)	Same
Regulation Number	882.5910	882.5910	Same
Product Code	GXQ	GXQ	Same
Materials	Bovine pericardium	Bovine pericardium	Same
Design	Various size patches	Various size patches	Same

Sterility	Chemical sterilization with 10^{-6} SAL	Chemical sterilization with 10^{-6} SAL	Same
Single Use	Yes	Yes	Same
Medical Specialists	Neurology	Neurology	Same
Packaging	Jar/Lid	Jar/Lid	Same
Storage solution	**0.2% glutaraldehyde**	**1% propylene oxide**	Different

Functional/Safety Testing:	The verification activities conducted indicate that DuraSure biologic patch meets the product performance requirements of the device specifications and does not raise any additional safety issues.
Sterilization:	DuraSure biologic patch is chemically sterilized according to ISO14160: 2011, "Sterilization of health care products -- Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization process for medical devices".
Biocompatibility:	The material for DuraSure Biologic Patch is bovine pericardium. It is identical to that in the predicate device and the reference device which have established biocompatibility. This submission is to expand the indication with no change to product design, materials, or manufacturing processes.
Summary of Product Testing:	The following tests have been completed to evaluate the safety and performance of the DuraSure Biologic Patch when compared with the predicate device: • Tensile test • Burst strength test • Suture retention test • Thickness measurement

Test	**Test method summary**	**Results**
Tensile	Use Instron pull the sample until it fails. Record the ultimate tensile strength in MPa.	All DuraSure patches passed the acceptance criteria of $\geq$ 2 MPa. The mean of tensile strength of the predicate device was measured as 7.0 MPa. The mean

		of tensile strength of DuraSure patch was measured as 11.9 MPa.
Elongation	Use Instron pull the sample until it fails. Record the elongation at the failure as percent of the original sample length.	All DuraSure patches passed the acceptance criteria of 5~50% elongation. The mean of elongation of the predicate device was measured as 32%. The mean of elongation of DuraSure patch was measured as 25%.
Burst strength	Sample is secured in the testing fixture as a membrane between two chambers. One side of the sample is slowly pressurized using water. Record the pressure at the time of burst or leak.	All DuraSure patches passed the acceptance criteria of ≥ 12 PSI. The mean of burst strength of the predicate device was measured as 59 PSI. The mean of burst strength of DuraSure patch was measured as 127 PSI.
Suture retention	Make sutures on the edge of the patch. Pull the suture using Instron until either patch or suture fail. Record the force at the failure.	All DuraSure patches passed the acceptance criteria of ≥ 300 gf. The mean of suture retention of the predicate device was measured as 978 gf. The mean of suture retention of DuraSure patch was measured as 970 gf.
Thickness	Measure the thickness of the patch using a thickness gauge	All DuraSure patches passed acceptance criteria of 0.35~0.75 mm. The thickness of the predicate device was measured between 0.32~0.71 mm.

Summary of Pre-clinical Study:	The purpose of this animal study was to assess the local tissue response to implantation following 1, 8, and 26-week brain dural repair/neural implantation in rabbits compared to a predicate control to satisfy ISO 10993-6, Annex D, Tests for local effects after implantation and US-FDA Guidance Document for Dura Substitutes Devices, Section XI, 2000. Forty nine (49) rabbits received single dural defects of approximately 0.6 cm x 0.6 cm. Test or control article were sutured in place to cover each dural defect. The bone flap was replaced, the dermal incisions were surgically closed, and animals were recovered and returned to standard housing. Animals were observed closely and weighed weekly to as one measure of general clinical health. After 1, 8, or 26 weeks post-surgery, animals were humanely euthanized and draining lymph nodes and the whole skull with brain was excised and placed in formalin. The formalin-fixed lymph nodes and implant sites were processed by histopathology techniques, using decalcification (as needed) and paraffin embedding. Resulting lymph node slides were stained with H&E. The dura/brain sections were treated with H&E, Fluoro-Jade, Luxol Fast Blue, anti-GFAP (glial fibrillary acidic protein) and anti-Iba-1 immunostaining on slides. All slides were evaluated by a veterinary pathologist for neuropathological changes in brain tissue, dural integrity, neoduralization and local tissue reaction according to ISO 10993-6 and FDA Guidance. The overall conclusion of the control and test article brain dural repair local effect evaluation based on in vivo and terminal evaluations, including an extensive histopathological evaluation of the implantation site, adjoining areas and draining lymph nodes, is that the implantation and dural repair surgery was successful and the test article is locally non-toxic. This applies to evaluations of animals exposed for 1, 8 or 26-weeks. General

	clinical evaluations/cageside observations, neurophysiological evaluations and body weights provide no evidence supporting an adverse effect of the surgery, control material or test article. These conclusions are supported by macroscopic evaluations and microscopic evaluations with scoring. Resorption of the test article or control article was minimal at the last exposure time evaluated. Adhesions at or near the repair site were noted, especially at one week exposure, and evidence of hydrocephaly was also noted, especially at 1 and 8 week exposure, however neither were associated with any pathology or adverse effects. From this investigation, it appears that the test and control articles performed equivalently in the in-vivo rabbit model of dural repair.
Conclusion:	LeMaitre Vascular has demonstrated that DuraSure Biologic Patch is substantially equivalent to the predicate devices based on its intended use and fundamental scientific technology.